



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,766	03/18/2004	Timothy Nicholas Ray	7544.100	4668

7590 04/13/2005

Thomas P. Liniak
Liniak, Berenato & White, LLC
Suite 240
6550 Rock Spring Drive
Bethesda, MD 20817

EXAMINER

FORD, VANESSA L

ART UNIT	PAPER NUMBER
----------	--------------

1645

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/802,766

Applicant(s)

RAY, TIMOTHY NICHOLAS

Examiner

Vanessa L. Ford

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-12, 31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group II, claims 13-30 filed on December 2, 2004 is acknowledged. Claims 1-12 and 31 and 32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

2. The use of the trademarks have been noted in this application. See page 15. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. The specification should be reviewed for these types of informalities and correction is required.

Claim Objections

3. The claims are objected to for the following informality; "Chlorella" is the genus of an organism and should be underlined or italicized at each occurrence in the claims. Correction is required.

4. The claims are objected to for the following informality: Claim 22 depends from a non-elected invention. Correction is required.

5. Applicant is advised that should claim 16 be found allowable, claim 17 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Drawings

6. Figure 1 is objected to because it does not appear to contain a figure. The figure or image is not visible. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 13-30 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13 in particular, recites the phrase "...a temperature of less than about zero degrees Celsius ...". It is unclear as to what the applicant is referring because there is no lower limit to the temperature range. Thus, the metes and bounds of the phrase cannot be ascertained. Clarification is required.

8. Claims 13-30 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13 in particular, recites the phrase "...less than about 5 microns ...", "less than about 2 microns ..." (claims 16-17), "... a diameter greater than about 0.1 microns" (claims 22-23). It is unclear as to what the applicant is referring because there is no lower/upper limit for the recited diameter ranges. Thus, the metes and bounds of the phrase cannot be ascertained. Clarification is required.

9. Claims 13-30 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13 in particular, recites the phrase "...sufficient period ...". It is unclear as to what the applicant is referring. What constitutes "a sufficient period"? Thus, the metes and bounds of the phrase cannot be ascertained. Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 13, 15-17, 22 and 30 are rejected under 35 U.S.C. 103(a) as unpatentable over Klyachko-Gurvich et al (*Sov Plant Physiol. Mar/Apr 1978 (transl. 1978), Vol. 25, No. 2, Pt. 2, p. 328-332*) in view of Meijer et al (*Biotechnology Techniques, May 1998, vol. 12, No. 5, p. 353-358*)

Claims 13, 15-17, 22 and 30 are drawn to a method of pulverizing *Chlorella*, comprising the steps of: providing a liquid solution comprising alcohol and *Chlorella*; maintaining the solution at a temperature of less than about zero degrees Celsius while sonicating the solution using an ultrasonic dismembrator for a sufficient period to achieve a solution with homogenously dispersed *Chlorella* diatoms having a diameter of less than about 5 microns.

Klyachko-Gurvich et al teach a method of mechanically damaging the cell wall of *Chlorella* (pulverizing) comprising mixing *Chlorella* cells, beads and organic solvents (including isopropanol or methanol) (page 329). Klyachko-Gurvich teach that the *Chlorella* solution cells were also placed in a disintegrator for further destruction (page 329).

Art Unit: 1645

Klyachko-Gurvich et al do not teach sonicating the solution at a temperature less than zero degrees Celsius.

Meijer et al teach a method of sonicating *Chlorella* for 10 minutes (a sufficient period) and maintaining the solution on ice (a temperature of less than about zero degrees Celsius) (page 354). Meijer et al teach that the *Chlorella* extracts were disrupted using a sonic disrupter (page 354). Therefore, the *Chlorella* diatoms are fractioned in sizes of from about 0.1 microns to about 5 microns since the instant specification teaches that the *Chlorella* solution undergoes ultrasonic dismembration (page 14 of instant specification). Claim limitations such as "including the step of maintaining the *Chlorella* in the solution at a temperature of about -1°C or colder during said maintaining and sonicating step" is taught by the prior art because the prior art teaches that the extracts are kept on ice (page 354). The claim limitation "the further step of terminating sonication prior to fragmenting a majority of the *Chlorella* diatoms into colloids having a diameter of less than about 2 microns" is taught by the prior art because the prior art teaches that extracts were disrupted using a sonic disrupter (page 354).

It would be *prima facie* obvious at the time the invention was made to modify the method of Klyachko-Gurvich et al to include sonicating the solution because Meijer et al teach that sonicating is a means of mechanically damaging the cell walls in order to extract or release protein (page 356). It would be expected barring evidence to the contrary that adding a sonification step to a method of mechanically damaging *Chlorella* cell walls would be effective at optimizing *Chlorella* fragments.

11. Claim 14 is rejected under 35 U.S.C. 103(a) as unpatentable over Klyachko-Gurvich et al and Meijer et al as applied to claims 13, 15-17, 22 and 30 above and in further view of Sennhenn et al (*U.S. Patent No. 6,684,525 published February 3, 2004*).

Claim 14 is drawn to the method of claim 13, including the step of super cooling the solution to about -15°C prior to said maintaining and sonicating step.

The teachings of Meijer et al and Kralovec et al have been described previously.

Meijer et al and Kralovec et al do not teach including the step of super cooling the solution to about -15°C prior to said maintaining and sonicating step.

Sennhenn et al teach that compositions can lyophilized (see the Abstract).

Sennhenn et al teach that the temperature for the crystallization in the case of an aqueous solution is between -60°C and 0°C (column 3). The claim limitation "wherein the super-cooling step is done prior to maintaining and sonicating" is taught by the prior art because the super-cooling step is performed in the lyophilizing phase.

It would be *prima facie* obvious at the time the invention was made to modify the method of Klyachko-Gurvich et al and Meijer et al as combined above because Sennhenn et al teach that the temperature for the crystallization in the case of an aqueous solution is between -60°C and 0°C (column 3 and column 5), thereby super-cooling the solution. It would be expected barring evidence to the contrary that adding

Art Unit: 1645

a step of super-cooling to about -15°C *Chlorella* cell walls would be effective at optimizing *Chlorella* fragments.

12. Claims 13, 15-17, 22 and 30 are rejected under 35 U.S.C. 103(a) as unpatentable over Meijer et al (*Biotechnology Techniques*, May 1998, vol. 12, No. 5, p. 353-358) in view of Kralovec (*U.S. Patent No. 6,551,596 B2 published April 22, 2003*).

Claims 13, 15-17, 22 and 30 are drawn to a method of pulverizing *Chlorella*, comprising the steps of: providing a liquid solution comprising alcohol and *Chlorella*; maintaining the solution at a temperature of less than about zero degrees Celsius while sonicating the solution using an ultrasonic dismembrator for a sufficient period to achieve a solution with homogenously dispersed *Chlorella* diatoms having a diameter of less than about 5 microns.

Meijer et al teach a method of sonicating (mechanically damaging the cell wall) (pulverizing) of *Chlorella* by providing a liquid solution of *Chlorella* and maintaining the solution on ice (a temperature of less than about zero degrees Celsius) and sonicating the solution for 10 minutes (a sufficient period) (page 354). Meijer et al teach that the *Chlorella* extracts were disrupted using a sonic disrupter (page 354). Therefore, the *Chlorella* diatoms are fractioned in fragments sizes of from about 0.1 microns to about 5 microns since the instant specification teaches that the *Chlorella* solution undergoes ultrasonic dismembration (page 14 of instant specification). Claim limitations such as "including the step of maintaining the *Chlorella* in the solution at a temperature of about -1°C or colder during said maintaining and sonicating step" is taught by the prior art

Art Unit: 1645

because the prior art teaches that the extracts are kept on ice (page 354). The claim limitation "the further step of terminating sonication prior to fragmenting a majority of the *Chlorella* diatoms into colloids having a diameter of less than about 2 microns" is taught by the prior art because the prior art teaches that extracts were disrupted using a sonic disrupter (page 354).

Meijer et al do not teach using an alcohol in the extraction method.

Kralovec teaches a method of extracting *Chlorella* and also teaches that ethanol is used to reduce the volume of the extract (column 6, lines 46-64). Kralovec teaches that the method of the extracting *Chlorella* uses ethanol in 80% by weight of alcohol (Example 1, column 12).

It would be *prima facie* obvious at the time the invention was made to use alcohol (ethanol) in a method of extracting *Chlorella* because Kralovec teaches that ethanol in 80% by weight of alcohol reduces the volume of the extract. It would be expected barring evidence to the contrary that adding a solvent such as ethanol to a method of extracting *Chlorella* would be effective optimizing the extracts produced in the process since the instant specification teaches that alcohol can be used to lower the surface tension, provide for ease of assimilation and act as a preservative (page 17 of the instant specification).

Status of Claims

13. No claims allowed.

Art Unit: 1645

14. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Vanessa L. Ford
Biotechnology Patent Examiner
February 25, 2005


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600